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09/555,529	07/24/2000	PATRICIA KANNOUCHE	192863US0PCT	6934

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT PAPER NUMBER

1634

NOTIFICATION DATE DELIVERY MODE

11/20/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/555,529	Applicant(s) KANNOUCHE ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 30-39, 43-63 and 66-78 is/are pending in the application.
4a) Of the above claim(s) 43-58 and 66-78 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 30, 34, 38 and 59-63 is/are rejected.
- 7) Claim(s) 32, 33, 35-37 and 39 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Alignment: SEQ ID NO: 25</u> |

DETAILED ACTION

1. This action is responsive to the Amendment filed August 6, 2007. Claims 30, 32-34, 39, 51-53, 56-60 have been amended, and claims 40-42, 64-65 and 79 have been canceled. Claims 43-58 and 66-78 remain withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Accordingly, claims 30-39 and 59-63 are now under consideration. Applicant's amendments and arguments have been thoroughly reviewed. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is NON-FINAL.**

Claim Objections

2. Claim 39 is objected to because of the following informalities: it recites "on a vector" rather than, e.g., "in a vector." Appropriate correction is required.
3. Claims 32-33 and 35-37 are objected to because of the following informalities: the claims depend from a rejected base claim.

Specification

4. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR 1.821 through 1.825 because the specification recite sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR 1.821(d). In particular, it is noted that the description of Figures 2A-E appears to contain multiple errors. First, the description identifies HsKin17 as SEQ ID

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NO: 25 and MmKin17 as SEQ ID NO: 26 (i.e., the reverse of the correct order).

Second, the description identifies SEQ ID NO: 2 as encoding MmKin17; however, SEQ ID NO: 2 is too short to encode this amino acid sequence, and further, SEQ ID NO: 2 corresponds to a polynucleotide encoding a deletion construct of the MmKin17 protein (see, e.g., text of claims 60-61). It appears that the nucleotide sequence identified as mmKin17.seq in Figure 2 may correspond to SEQ ID NO: 24; however, applicant should review this sequence to ensure that this is correct, and make the necessary amendments/ corrections to the description of Figure 2. Appropriate corrections for compliance are required.

Claim Rejections - 35 USC § 112, first paragraph

5. In view of the cancellation of claims 40-42 and 64-65, the new matter rejection of these claims set forth in the prior Office action of April 5, 2007 is moot.

6. In view of the amendment of claim 39 limiting the claim to a human cell comprising "the isolated polynucleotide of Claim 31 on a vector, wherein the vector is pCMVkin17 Δ HR," the new matter rejection of this claim set forth in the prior Office action of April 5, 2007 is withdrawn. The specification discloses human cells comprising this vector at, e.g., page 24-25 and 27-29. Further, the construction of the vector pCMVkin17 Δ HR is described in the specification at pages 24-25, such that the claimed cells could be made or isolated without undue experimentation (note in particular the disclosure in Bourdon et al [Oncogene 14:85-94 [1997] at page 93, left column, regarding the manner in which pCMVDT21 is prepared from the readily available vector

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pCMV β). Thus, no deposit is required under 35 USC 112, first paragraph (see *MPEP* 2404.01 and 2404.02).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 30 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The claims have been evaluated in accordance with the Guidelines for Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" Requirement (*66 Fed. Reg. 1099 [01/05/2001]*) and in accordance with the guidance provided in *MPEP* 2163.

It is first noted that each of claims 30 and 59 recite groups of sequences from which the "nucleotide sequence" of the claims is selected. This rejection applies to claim 30 to the extent that the claim is drawn to an isolated polynucleotide comprising "a nucleotide sequence which encodes a human kin17 protein which comprises the amino acid sequence in SEQ ID NO:26" and to claim 59 to the extent that the claim is drawn to an isolated polynucleotide "consisting of a nucleotide sequence which encodes a mouse kin17 protein which comprises the amino acid sequence in SEQ ID NO:25." The other

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sequences encompassed by claims 30 and 59 are deletion constructs generated by applicants and therefore do not encompass molecules such as genes.

Claim 30 is drawn to an isolated polynucleotide comprising "a nucleotide sequence which encodes a human kin17 protein which comprises the amino acid sequence in SEQ ID NO:26." Claim 59 is drawn to an isolated polynucleotide "consisting of a nucleotide sequence which encodes a mouse kin17 protein which comprises the amino acid sequence in SEQ ID NO:25." While the specification does teach the complete amino acid sequences of human kin17 and mouse kin17, as well as cDNA sequences encoding them, the claims as written encompass any isolated nucleic acid that encodes the amino acid sequences set forth in SEQ ID Nos 26 and 25. Thus, the claims as written encompass the human gene that encodes SEQ ID NO: 26, and the mouse gene that encodes SEQ ID NO: 25.

Possession of an invention may be shown in many ways. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by (a) actual reduction to practice, (b) a clear depiction of the invention in drawings or in structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the invention as a whole, or (c) a description of sufficient, relevant, identifying characteristics (i.e., structure or other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics) such that a person of skill in the art would recognize that applicant had possession of the claimed genus. A "representative number of

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species” means that the species which are adequately described are representative of the entire genus.

Possession may be shown by describing an actual reduction to practice of the claimed invention. In the instant case, Applicant has disclosed the cDNA sequences encoding SEQ ID Nos 26 and 25, and has thus reduced these particular species to practice. It is noted that the instant claims encompass any cDNA encoding SEQ ID Nos 26 and 25, not just the particular cDNA sequences disclosed by applicants. Given that the genetic code is well known, a skilled artisan could readily envision other cDNAs encoding instant SEQ ID NOS 26 and 25, and would recognize that applicants had possession of such cDNAs at the time the invention was made (i.e., the particular species taught by applicant are in fact representative of a genus of cDNAs encoding SEQ ID NOS 26 and 25). However, the instant claims are not limited to such cDNA molecules, but rather encompass a broader genus of nucleic acids that includes human and mouse genes encoding instant SEQ ID Nos 26 and 25, respectively. One of skill in the art would recognize that the genus of the instant claims embraces nucleic acids including additional sequences such as promoter(s), introns, enhancer(s), etc. The specification at page 2 (last paragraph) teaches that “The chromosomal localization of the gene encoding the murine kin17 protein has been performed by in situ hybridization and found to be on chromosome 2 in mice” and that “The human Kin17 gene is located on chromosome 10p15-p14.” However, applicant has not disclosed the sequences of these genes, nor has applicant, e.g., separately disclosed promoter, enhancer, intronic sequences, etc., for these kin17 genes. As applicant has not disclosed any such gene

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sequences, the species that have been reduced to practice (specifically, the cDNA sequences noted above) are not representative of the genus of nucleic acids embraced by the claims. Particularly, applicant has not reduced to practice any species representative of a human or mouse kin17 gene.

Possession of an invention may also be shown by a clear depiction of the invention in drawings or in structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the invention as a whole. However, in the instant case, applicant has not provided any such depiction of the genes noted above for which a description is lacking.

Finally, possession of an invention may be shown by disclosure of detailed, relevant, identifying characteristics sufficient to show possession of the claimed genus. However, in the instant case, applicants have not provided either a disclosure of the complete gene sequences for human and/or mouse kin17, or, e.g., provided any kind of other descriptive information that would be sufficient to show possession of the claimed genus (for example, a separate disclosure of the various regulatory or intronic sequences that characterize kin17 and the relative positions of those sequences in the gene, etc.). It is noted that MPEP 2163 states that "For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length." While such characteristics have clearly been provided by applicant with respect to the cDNAs noted above, applicant has not provided any of this descriptive information with respect to the genes now encompassed by the claims. Thus, while one of skill in the art would have recognized that applicant

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was in possession of cDNAs encoding SEQ ID Nos 26 and 25, such cDNAs are not representative of the much broader genus of the instant claims, which encompass the genes encoding human and mouse kin17. Therefore, a person of skill in the art would not consider applicant to be in possession of the genus encompassed by the instant claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 34, 38, and 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 38 are indefinite over the recitation of the limitation "with the exception that amino acids 129 to 228 are deleted" in claim 34. This language does not make clear whether "129 to 228" refers to SEQ ID NO: 26 or to the protein "which comprises" it, such that the properties of the polynucleotide encompassed by the claims are not clear. This rejection could be overcome by amending the claim such that it recites, e.g., "with the exception that amino acids 129 to 228 are deleted in SEQ ID NO: 26, and comprises...."

Claims 60-63 are indefinite over the recitation of the limitation "the amino acid sequence wherein amino acids 129 to 228 are deleted in SEQ ID NO:25" in claim 60. It is noted that claim 59 (from which claim 60 depends) refers to "the amino acid sequence in SEQ ID NO: 25 with the exception that amino acids 129 to 228 are deleted

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in SEQ ID NO:25," but not to any "amino acid sequence wherein amino acids 129 to 228 are deleted in SEQ ID NO:25." The latter language does not clearly refer back to a sequence set forth in claim 59. This rejection could be overcome by amending the claim to refer to, e.g., "the amino acid sequence in SEQ ID NO: 25 wherein amino acids 129 to 228 are deleted in SEQ ID NO:25."

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Angulo et al (Nucleic Acids Research 19(19):5117-5123 [1991]), as evidenced by the teachings of the specification.

Claim 59 encompasses an isolated polynucleotide that "encodes a mouse kin17 protein which comprises the amino acid sequence in SEQ ID NO: 25." Angulo et al teach a cDNA encoding mouse kin17 having an amino acid sequence that is identical to that of instant SEQ ID NO: 25 with the exception of two amino acids at positions 23-24 of the protein (see alignment enclosed herewith)(see entire Angulo et al reference, particularly Figure 1). An inspection of Figure 1 of Angulo et al reveals that this two amino acid difference results from a single G-C transposition at nucleotides 93-94 of the sequence disclosed by Angulo et al as compared to the sequence set forth by applicant in Figure 2 (apparently instant SEQ ID NO: 24; note error in Figure legend referenced

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above). Applicant's specification appears to disclose only the use of the mouse kin17 cDNA sequence of Angulo et al (see, e.g., Example 5, particularly the top of page 24, describing the cloning of Angulo et al's sequence for use in expression assays; see also the reference to the sequence of Angulo et al at page 2). Further, the specification does not describe, e.g., the sequencing of any novel variant of mouse kin17, or provide any description or disclosure with respect to the sequence set forth in SEQ ID NO: 25 that would lead one of skill in the art to conclude that this represents a novel mouse sequence; rather, the teachings of the specification appear to indicate only the use of the prior art clone/sequence of Angulo et al in various assays, in the construction of new deletion constructs, etc. Further, as noted above, the description of Figure 2 (which provides both the amino acid and nucleotide sequences of mouse Kin17) contains multiple errors/misidentifications of sequences set forth therein. Accordingly, it appears that the only difference between applicant's sequence and that of Angulo et al is a typographical error, and that the actual polynucleotide and protein employed by applicants was in fact that of Angulo et al. Thus, Angulo et al anticipate the claimed invention.

Conclusion

13. An alignment of SEQ ID NO: 25 with the mouse Kin17 protein sequence of Angulo et al is cited to illustrate the 2 amino acid difference between the protein disclosed by applicants and that disclosed by Angulo et al.

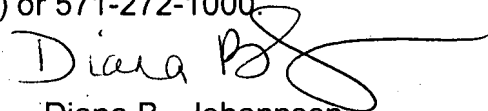
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Diana B. Johannsen
Primary Examiner
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